

ADDENDUM A
BUSINESS ASSOCIATE AGREEMENT

In the course of satisfying its contractual obligations to Practice pursuant to the Practice's engagement of CDR, CDR is performing a function or activity on behalf of Practice that constitutes CDR a "Business Associate" of Practice within the meaning of the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (45 CFR § 160 and 164, as amended) ("HIPAA"). The purpose of this Appendix is to provide the Practice with satisfactory assurance that, as Practice's Business Associate, CDR will comply with the privacy and security requirements concerning Business Associates imposed by HIPAA and its implementing regulations as amended. Accordingly, CDR and Practice agree as follows:

I. GENERAL PROVISIONS

Section 1. **Effect.** The terms and provisions of this Appendix shall supersede any other conflicting or inconsistent terms and provisions in the Master Agreement to which this Appendix is attached, including all exhibits or other attachments thereto and all documents incorporated therein by reference.

Section 2. **Amendment.** CDR and Practice agree to amend this Appendix to the extent necessary to allow Practice or the CDR to comply with the Standards for Privacy of Individually Identifiable Health Information (45 CFR § 160 and 164, as amended) (hereinafter "Privacy Standards"), the Standards for Electronic Transactions (45 CFR § 160 and 162), and the Security Standards (45 CFR § 160, 162 and 164), all as modified or supplemented by the HITECH Act 42 U.S.C. §3000 et. seq., and implementing regulations and guidance (collectively, the "Standards") promulgated, or to be promulgated, by the Secretary or other authorized agencies. The CDR agrees to develop amendments to this Appendix to incorporate any material provisions required by the Standards, and to distribute the same to Practice for adoption. Any amendment distributed by CDR shall be deemed to be accepted by Practice unless CDR is notified by Practice of any objections within thirty (30) days of its receipt of such amendment. Each Party is responsible for determining the adequacy of the amendment for its compliance with HIPAA.

Section 3. **Definitions.** Capitalized terms used herein without definition shall have the respective meanings assigned to such terms in the Agreement, or Part V of this Appendix.

II. OBLIGATIONS OF CDR

Section 1. **Use and Disclosure of Protected Health Information.**

a. CDR may use and disclose Practice's PHI only as permitted under the Master Agreement and this Appendix A. CDR shall use reasonable measures to ensure that its directors, officers, employees, subcontractors, business partners, and agents do not use or disclose Practice's PHI received from Practice in any manner that would constitute a violation of the Privacy Standards if done by Practice, except that CDR may use and disclose Practice's PHI to CDR's subcontractors and others: (i) for CDR's proper management and administration if CDR enters into a written agreement with a party to whom it releases Practice's PHI, and uses reasonable measures to require such party to hold such Practice's PHI confidentially, to further use or disclose it only as required by law or for the purpose for which it was disclosed, and to notify CDR of any instances of which it becomes aware in which the confidentiality of the Practice's PHI is breached in a manner consistent with CDR's obligations under this Appendix; (ii) to carry out CDR's legal responsibilities hereunder, or as otherwise required by law or regulation; (iii) to provide Data Aggregation services relating to the health care operations of Practice and other hospitals or health systems with which CDR contracts; (iv) to deidentify Practice's PHI it receives from Practice, if any, pursuant to 45 CFR § 164.514, which De-identified Data, and any derivative works from such data, shall be owned by CDR, in all forms and media worldwide, and may be used by CDR for any lawful purpose; or (v) to create and disclose a Limited Data Set, provided that the conditions set forth in Section 9 of this Appendix are satisfied.

b. Effective not later than February 17, 2010, or such later date as may be specified pursuant to the HITECH Act, CDR shall limit its uses and disclosures of Practice's PHI to uses and disclosures that comply with the Business Associate

requirements of 45 CFR §164.504 (e) (2). The foregoing shall not be construed to limit the responsibility of the CDR under the Master Agreement and this Appendix as in effect prior to February 17, 2010.

c. Effective February 17, 2010, CDR shall determine the Minimum Necessary Protected Health Information to be disclosed for uses, disclosures or requests of or for Practice's PHI, other than those that exempt from the Minimum Necessary requirement specified in 45 CFR § 164.502(b)(2), in order to accomplish the intended purpose of the use, disclosure, or request, consistent with the terms of the Master Agreement. To the extent practicable and consistent with the terms of the Master Agreement, as determined by CDR, the Minimum Necessary shall be the information contained in a Limited Data Set, as defined in 45 CFR § 164.514(e)(2). At such time as the Secretary issues guidance on what constitutes the "Minimum Necessary" for purposes of the HIPAA Privacy Rule, CDR shall provide Practice with an amendment to this section which complies with the guidance, which shall replace this Section 1.c. as of the effective date of the guidance.

d. Effective not later than six (6) months after the date on which the Secretary publishes applicable final regulations, CDR shall not, directly or indirectly, receive remuneration in exchange for Practice's PHI unless CDR or the Practice has obtained to an authorization from the subject individual(s) which complies with all applicable requirements or unless an exception specified in Section 13405(d)(2) of the HITECH Act, 42 U.S.C. § 17935(d)(2) or regulations published by the Secretary applies. CDR shall not rely on any of the foregoing exceptions as to Practice's PHI without advance notice to all Practices which describes the types of circumstances and the applicable exceptions to be relied upon by the CDR. Such notice may be made through notice published on the USWR web site.

Section 2. **Safeguards Against Misuse of Information**. CDR agrees that it shall use reasonable safeguards to prevent the use or disclosure of Practice's PHI except as otherwise provided for in this Appendix and the Master Agreement or as otherwise permitted by the Standards. Such safeguards shall include the implementation and maintenance of reasonable and appropriate administrative, technical, and physical safeguards to protect the security, integrity, confidentiality, and availability of Practice's PHI created, maintained, received, or transmitted by CDR. CDR shall further use reasonable measures to ensure that any agent to whom it provides Practice's PHI, including a subcontractor, agrees to implement reasonable and appropriate safeguards to protect such Practice's PHI. Effective not later than February 17, 2010, or such later date as may be specified pursuant to the HITECH Act, CDR shall fulfill the foregoing responsibilities by being in compliance with the provisions of the HIPAA Standards for Privacy of Individually Identifiable Health Information set forth at 45 CFR § 164.308 (Administrative Safeguards); 45 CFR § 164.310 (Physical Safeguards); 45 CFR § 164, 312 (Technical Safeguards) and 45 CFR § 164.316 (Policies and Procedures and Documentation Requirements) (collectively, the "Security Requirements") in the same manner as the Security Requirements apply to a Covered Entity under HIPAA. CDR shall also comply with additional or modified requirements set forth in any Annual Guidance as to the Security Requirements published by the Secretary and with the additional requirements of the HITECH Act that relate to security of Practice's PHI.

Section 3. **Reporting of Disclosures of Protected Health Information or Security Incidents**.

a. CDR shall maintain systems to monitor and detect a Breach of Unsecured Protected Health Information accessed, maintained, retained, modified, stored, destroyed or otherwise held or used in Unsecured form by CDR, whether the Unsecured Protected Health Information is in paper or electronic form. CDR shall provide to notice of a Breach involving Practice's PHI within five (5) business days of the first day the Breach is known, or reasonably should have been known, to the CDR, including for this purpose any employee, officer, or other agent of the CDR (other than the individual committing the Breach). The notice shall include the identification of each individual whose Unsecured Protected Health Information was, or is reasonably believed to have been, subject to the Breach and the circumstances of the Breach, as both are known to CDR at that time. The notice shall be given via email to Practices Privacy Officer, as identified by Practice on the USWR website. The Parties agree that notice in accordance with the foregoing satisfies the notice requirements of this Section 3. Following the notice, CDR shall conduct such further investigation and analysis as is reasonably required, and shall promptly advise Practice of additional information pertinent to the Breach which CDR obtains. CDR shall cooperate with Practice to support the provision of required notices in a timely manner, including the determination of whether the use, access, or disclosure is one that "poses a significant risk of financial, reputational, or other harm to the individual", thereby requiring notice. Practice

is responsible for the provision of notice in a timely manner, provided that Practice shall consult with CDR in good faith regarding the details of the notice.

b. CDR shall also, promptly on becoming aware of it, report any Security Incident involving Practice's PHI to Practice, unless the Security Incident was the subject of a notice under Section 3.a.

Section 4. **Agreements with Third Parties.** CDR shall obtain and maintain an agreement with each of the CDR subcontractors or agents that has or shall have access to Practice's PHI, which is received from, or created or received by CDR on behalf of Practice, pursuant to which agreement such subcontractor or agent agrees to be bound by restrictions, terms and conditions that are consistent with those applicable to CDR pursuant to this Appendix and the Agreement with respect to such Practice's PHI, provided however that this Section shall not apply to disclosures by CDR of a Limited Data Set, as such disclosures shall be governed by Section 9 of this Appendix.

Section 5. **Access to Information.** Within twenty (20) days of a request by Practice for access to Practice's PHI about an individual contained in a Designated Record Set so that it may respond to said individual's request for such information, CDR shall make available to Practice such Practice's PHI provided that such Practice's PHI constitutes a Designated Record Set, such determination to be made by CDR. In the event any individual requests access to Practice's PHI directly from CDR, CDR shall within twenty (20) days forward such request to Practice. Any denials of access to the Practice's PHI requested shall be the responsibility of Practice.

Section 6. **Availability of Protected Health Information for Amendment.** Within twenty (20) days of receipt of a request from Practice for the amendment of an individual's Practice's PHI, or a record regarding an individual maintained by CDR in a Designated Record Set, CDR shall provide such information to Practice for amendment, and incorporate any such amendments in the Practice's PHI as required by 45 CFR § 164.526.

Section 7. **Accounting of Disclosures.**

a. Within twenty (20) days of notice by Practice to CDR that it has received a request from a patient for an accounting of disclosures of Practice's PHI, other than related to the treatment of the patient, the processing of payments related to such treatment, or the operation of Practice or its business associate, and not relating to disclosures made earlier than the later of six (6) years prior to the date on which the accounting was requested or April 14, 2003, the effective date of the Privacy Standards, CDR shall make available to Practice such information as is in CDR possession and that is required for Practice to make the accounting required by 45 CFR § 164.528. In the event the request for an accounting is delivered directly to CDR, CDR shall, within twenty (20) days, forward such request to Practice. CDR hereby agrees to implement an appropriate recordkeeping process to enable it to comply with the requirements of this Section.

b. In addition, Practice shall advise CDR in writing if Practice uses or maintains an Electronic Health Record(s) ("EHR") through which disclosures of Practice's PHI are made and of the effective date upon which the requirement to provide an Accounting for EHR disclosures for purposes of Treatment, Payment and Health Care Operations ("TPO Accounting") is effective as to Practice. Such notice shall be provided to the CDR in writing at least thirty days (30) in advance of the date the requirements to provide a TPO Accounting are applicable to Practice ("TPO Notice Period"). CDR shall capture and store information required for a TPO Accounting for EHR disclosures of Practice's PHI through or by CDR for a minimum of a rolling three (3) year period beginning with the later of the date specified in the Practice's notice or the end of the TPO Notice Period, in accordance with the applicable regulations published by the Secretary. From and after the effective date specified in the Practice's notice, CDR shall, as instructed by the Practice, either provide the TPO Accounting directly to the individual making the request or provide the information required for the TPO Accounting to the Practice. In either case, the information required for the TPO Accounting shall be available to the individual or to the Practice, as appropriate, within twenty (20) days of CDR's receipt of a request. To the extent not expressly prohibited by the HIPAA, the CDR reserves the right to make a reasonable charge to Practice for each TPO Accounting provided to Practice or to an individual at Practice's request.

Section 8. **Availability of Books and Records.** CDR hereby agrees to make its internal Practices, books, and records relating to the use and disclosure of Practice's PHI received from, or created or received by CDR on behalf of, Practice available to the Secretary for purposes of determining Practice's compliance with the Privacy Standards, as requested in writing by Practice.

Section 9. **Data Use Agreement.**

Section 9.1. **Activities.** The Parties agree that CDR may use and disclose a Limited Data Set for purposes of wound care and hyperbaric medicine research initiated by CDR, or as otherwise permitted by the Privacy Standards or Required by Law. Such Limited Data Sets need not be for the use of the Practice but CDR shall endeavor to make any resulting research studies, articles or similar results generally be made available to Practice through posting on the CDR website or through publication. CDR shall use reasonable measures to ensure that its directors, officers, employees, contractors, and agents do not use or disclose a Limited Data Set in any manner that would constitute a violation of the Privacy Standards if used or disclosed by Practice. CDR agrees not to use a Limited Data Set in such a way as to identify any individual, and further agrees not to contact any individual. The activities referred to in Section 9.1 of this Appendix shall collectively be referred to as the "Activities".

Section 9.2. **Limited Data Set.** Practice agrees that CDR may derive directly or through a subcontractor who is bound by terms and conditions consistent with CDR's obligations under this Appendix a Limited Data Set from Practice's PHI otherwise provided to CDR pursuant to the Master Agreement and use that Limited Data Set including in combination with other data in the performance of the Activities, provided, however, that no Limited Data Set created by CDR shall include any direct identifiers set forth at 45 CFR § 164.514(e)(2).

Section 9.3. **Safeguards Against Misuse of Information.** CDR shall use reasonable safeguards to prevent the use or disclosure of a Limited Data Set other than as permitted under this Agreement.

Section 9.4. **Reporting of Wrongful Disclosures.** CDR shall, within twenty (20) days of becoming aware of any use or disclosure of a Limited Data Set in violation of the Agreement by CDR, its officers, directors, employees, contractors, or agents, or by a third party to which CDR disclosed a Limited Data Set, report any such disclosure to Practice.

Section 9.5. **Agreements with Third Parties.** CDR shall obtain and maintain an agreement with each third party that has or will have access to a Limited Data Set, which satisfies the requirements for a Data Use Agreement, as set forth in 45 CFR § 164.514(e)(4), with respect to the Limited Data Set.

III. OBLIGATIONS OF PRACTICE

Section 1. Practice shall be responsible for assuring Practice's compliance with the HIPAA Standards.

Section 2. Practice shall provide CDR with at least thirty (30) days advance written notice of any restrictions on uses and disclosures of Practice's PHI that it agrees to, pursuant to 45 CFR §164.522, which will affect the uses and disclosures of Practice's PHI, which CDR is permitted to make pursuant to the Master Agreement, including this Appendix A.

IV. TERMINATION OF AGREEMENT

Section 1. **Termination Upon Breach of Provisions Applicable to Protected Health Information or Practice's Obligations.** Any other provision of this Appendix or the Master Agreement notwithstanding, the Master Agreement and this Appendix may be terminated by the Practice upon thirty (30) days written notice to CDR in the event that CDR breaches any provision contained in this Appendix, which notice shall describe the breach in reasonable detail. If such breach is not cured within such thirty (30) day period; provided, however, that in the event that termination of this Agreement is not feasible, in Practice's sole discretion, CDR hereby acknowledges that Practice shall have the right to report the breach to the Secretary, notwithstanding any other provision of this Agreement to the contrary. Effective February 17, 2010, in the event that CDR becomes aware of a pattern of activity or a practice of the Practice that constitutes a material violation of the obligations of

Practice under its this Appendix, CDR shall provide Practice with written notice describing the material violation in reasonable detail and a period of not less than thirty (30) days after receipt of such notice to cure the material violation. If such breach is not cured within such thirty (30) day period, CDR may terminate the Master Agreement and this Appendix on notice to Practice provided, however, that in the event that termination of the Master Agreement and this Appendix is not feasible, in CDR's sole judgment, Practice hereby acknowledges that CDR shall have the right to report the breach to the Secretary, notwithstanding any other provision of this Agreement to the contrary.

Section 2. **Return or Destruction of Protected Health Information Upon Termination**. Practice and CDR have determined that return or destruction of Practice's PHI is not feasible upon termination of the Agreement. Therefore, CDR shall have the applicable rights and shall comply with the applicable requirements of this Appendix for so long as Practice's PHI is held by CDR. In the event that CDR determines that it shall no longer maintain such Practice's PHI, it shall either return such Practice's PHI to Practice or destroy it (with certification of such destruction) at the sole option of CDR. The terms and provisions of this Appendix shall survive termination of the Agreement, and such Practice's PHI shall be used or disclosed solely for such purpose or purposes which prevented the return or destruction of such Practice's PHI, and shall be maintained as confidential. Aggregate data, De-identified Data shall not be subject to this obligation. Practice's PHI contained in a Limited Data Set shall continue to be governed by the Data Use Agreement provisions of Section 9 of this Appendix.

V. DEFINITIONS FOR USE IN THIS APPENDIX

"Data Aggregation" shall mean, with respect to Practice's PHI created or received by CDR in its capacity as the Business Associate of Practice, the combining of such Practice's PHI by CDR with the Practice's PHI received by CDR in its capacity as a Business Associate of another Practice, to permit data analyses that relate to the health care operations of the respective Practices. "De-identified Data" shall have the meaning set forth in 45 CFR § 164.514 regarding de-identification of Practice's PHI.

"Designated Record Set" shall have the meaning set forth in 45 CFR § 164.501.

"Electronic Media" shall mean the mode of electronic transmissions. It includes the Internet, extranet (using Internet technology to link a business with information only accessible to collaborating parties), leased lines, dial-up lines, private networks, and those transmissions that are physically moved from one location to another using magnetic tape, disk, or compact disk media.

"E PHI" or "Electronic Protected Health Information" or "Practice's E PHI" shall have the same meaning as the term "electronic protected health information" at 45 CFR § 160.103.

"Health Care Operations" shall have the meaning set forth in 45 CFR § 164.501.

"HITECH Act" shall mean the provisions of Division A, Title XIII of the American Recovery and Reinvestment Act of 2009 ("ARRA"), known as The Health Information Technology for Economic and Clinical Health, Act 42 U.S.C. §3000 et. seq., and implementing regulations and guidance including all implementing regulations and other official guidance, set forth.

"Individually Identifiable Health Information" shall mean information that is a subset of health information Practice's PHI information collected from an individual, and: (i) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and (ii) relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of health care to an individual; and (a) identifies the individual, or (b) with respect to which there is a reasonable basis to believe the information can be used to identify the individual.

"Limited Data Set" shall have the meaning ascribed to it in 45 CFR § 164.514 (e) (1).

"Master Agreement" shall mean the USWR Master Agreement between the Parties including any general policies, supplements or notices posted on the USWR website (www.USWoundRegistry.com).

“Practice’s PHI” shall mean the Protected Health Information of the Practice to which the Master Agreement and this Appendix applies.

“Privacy Standards” shall mean the Standard for Privacy of Individually Identifiable Health Information, 45 CFR § 160 and 164.

“PHI”, “Protected Health Information” or “Practice’s PHI” shall mean Individually Identifiable Health Information that is: (i) transmitted by electronic media; (ii) maintained in any medium constituting Electronic Media; or (iii) transmitted or maintained in any other form or medium or Activity Data as that term is used in the Agreement. Under no circumstances shall aggregate data or De-identified Data constitute “Protected Health Information” or “Practice’s PHI”. “Protected Health Information” or “Practice’s PHI” shall not include: (i) education records covered by the Family Educational Right and Privacy Act, as amended, 20 U.S.C. §1232g; and (ii) records described in 20 U.S.C. §1232g(a)(4)(B)(iv).

“Research” shall have the meaning set forth in 45 CFR § 164.501.

“Secretary” shall mean the Secretary of the Department of Health and Human Services or such other federal agency as is authorized to publish regulations or guidance pursuant to the HITECH Act.

“Security Incident” shall mean the attempted or successful unauthorized access, use, disclosure, modification, or destruction of information, or interference with systems operations in an information system.

“Security Standards” shall mean the Health Insurance Reform Security Standards at 45 CFR §160, 162, and 164.

All other defined terms in this Business Associate Agreement have the meaning assigned in the HITECH Act, unless otherwise defined in the HIPAA Privacy Rule or the HIPAA Security Rule.